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Eisai Co., Ltd.

EISAI TO PRESENT LATEST DATA ON NEUROLOGY PRODUCTS AND PIPELINES AT THE AMERICAN ACADEMY OF NEUROLOGY ANNUAL MEETING

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that the company will conduct presentations, including the latest data of the investigational anti-amyloid beta (Aβ) protofibril antibody lecanemab (development code: BAN2401), its dual orexin receptor antagonist lemborexant (product name: Dayvigo®) and its antiepileptic drug perampanel (product name: Fycompa®), at the Virtual American Academy of Neurology (AAN 2021) Annual Meeting from April 17 to 22, 2021.

As major presentations, an oral presentation regarding lecanemab will be given on the preliminary analysis for results of changes in brain-Aβ levels and amyloid-related imaging abnormalities-edema (ARIA-E) as observed in subjects of the ongoing open-label extension of the Phase II study (Study 201) for early Alzheimer's disease (AD) patients. Poster presentations regarding lemborexant are also planned, including the results of a pilot study evaluating next-dose transition from zolpidem to lemborexant for insomnia treatment. Additionally, for perampanel, a global pooled analysis results from the real-world experiences including early adjunctive use or monotherapy will be presented at poster sessions.

Eisai considers neurology a therapeutic area of focus. Eisai strives to create innovative products in therapeutic areas with high unmet medical needs as soon as possible, and will further contribute to addressing the diverse needs of, as well as increasing the benefits provided to, those living with the disease and their families.

AD/Dementia Oral Presentation:

Asset in Product/Development Oral presentation number Session	**Presentation Title** **Scheduled Date and Time (local time: Eastern Daylight Saving Time)**
Lecanemab S19-001 Aging and dementia	Preliminary Analysis of BAN2401 Effects On Brain Amyloid And ARIA-E Findings Over 12 Months Of Treatment In The Open-Label Extension Of The Phase2b Study BAN2401-G000-201 In Subjects With Early Alzheimer's Disease April 20 (Tue) 14:00 -15:00

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AD/Dementia Poster Presentation:

Asset in Product/Development Poster Number Session	**Poster Title**
Lecanemab P1-017 Aging and dementia	Baseline Characteristics for Clarity AD: A Phase 3 Placebo-Controlled, Double-Blind, Parallel-Group, 18-Month Study Evaluating BAN2401 in Early Alzheimer's Disease

Insomnia Poster Presentations:

Asset in Product/Development Poster Number Session	**Poster Title**
Insomnia P26-005 Insomnia and therapeutic option	Insomnia treatments and on-the-road driving performance: a systematic literature review
Leborexant P26-007 Insomnia and therapeutic option	Evaluation of Next-Dose Transition from Zolpidem to Lemborexant for the Treatment of Insomnia: A Multicenter Open-label Pilot Study
Leborexant P26-008 Insomnia and therapeutic option	Effect of Lemborexant on Fatigue Severity and Sleep Outcomes Over 12 Months in Subjects With Clinically Significant Fatigue at Baseline
Leborexant P26-009 Insomnia and therapeutic option	Responder Profiles Over 12 Months for Sleep Onset and Sleep Maintenance Outcomes with Lemborexant
Leborexant P26-010 Insomnia and therapeutic option	Effect of Lemborexant on Patient-Reported Distress About Sleeping and Interference with Daily Functioning in Subjects With Insomnia

Epilepsy Poster Presentations:

Asset in Product/Development Poster Number Session	**Poster Title**
Perampanel P7-001 Epilepsy and Clinical Neurophysiology	PROVE Study 506: Analysis of a Retrospective, Phase IV Study of Perampanel in Real-World Clinical Care of Patients Based on Study Site Participation in Previous Clinical Trials
Perampanel P7-007 Epilepsy and Clinical Neurophysiology	Efficacy and Safety of Low-and High-Dose Perampanel as First Adjunctive Therapy in Patients with Partial-Onset Seizures (POS): Post Hoc Analysis of the FAME Study
Perampanel P7-008 Epilepsy and Clinical Neurophysiology	Perampanel Monotherapy Beyond Initial Titration to Achieve Seizure Freedom in Patients with Partial-Onset Seizures (POS), with/without Secondarily Generalized Seizures (SGS): Post Hoc Analysis of Phase III Study 342 (FREEDOM)
Perampanel P7-009 Epilepsy and Clinical Neurophysiology	Long-term Evaluation of Adjunctive Perampanel on Mental Health in Pediatric Patients with Partial-Onset Seizures (POS) or Primary Generalized Tonic-Clonic Seizures (PGTCS) in Study 311

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Asset in Product/Development Poster Number Session	**Poster Title**
Perampanel P7-010 Epilepsy and Clinical Neurophysiology	Long-Term (1-Year) Seizure Freedom with Adjunctive Perampanel in Pediatric Patients (Aged 4–<12 Years) with Partial-Onset Seizures (POS) or Primary Generalized Tonic-Clonic Seizures (PGTCS): Post Hoc Analysis of Study 311
Perampanel P7-018 Epilepsy and Clinical Neurophysiology	ELEVATE Study 410 initial results: Phase IV study of perampanel as monotherapy or first adjunctive therapy in patients aged ≥ 4 years with partial-onset or primary generalized tonic-clonic seizures
Perampanel P7-019 Epilepsy and Clinical Neurophysiology	Efficacy and Safety of Adjunctive Perampanel for Myoclonic and Absence Seizures: Post Hoc Pooled Analysis of Adult, Adolescent, and Pediatric Patients in Studies 332, 311, and 232
Perampanel P7-020 Epilepsy and Clinical Neurophysiology	Perampanel Monotherapy for the Treatment of Epilepsy: Evidence From a Clinical Trial and Real-World Use
Perampanel P7-021 Epilepsy and Clinical Neurophysiology	Effectiveness and Tolerability of Perampanel in Epilepsy Patients Treated in Routine Clinical Practice: a Global Pooled Analysis Study
Perampanel P7-109 Epilepsy and Clinical Neurophysiology	Health State Utility Values in Paediatric Subjects with Partial Onset Seizures (POS) or Primary Generalized Tonic Clonic Seizures (PGTCS) receiving Adjunctive Perampanel
Perampanel P7-111 Epilepsy and Clinical Neurophysiology	Perampanel Monotherapy in Epilepsy Patients with Focal and Generalized Seizures: Real-World Experience
Perampanel P7-117 Epilepsy and Clinical Neurophysiology	Perampanel as Early Add-on Therapy for Epilepsy Patients with Focal and Generalized Seizures Treated in Clinical Practice
Lorcaserin P7-017 Epilepsy and Clinical Neurophysiology	MOMENTUM (Study 304): A Multicenter, Phase III, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Study of Adjunctive Lorcaserin (LOR) in Patients with Dravet Syndrome (DS)

Biogen AD/Dementia Poster Presentation:

Asset in Product/Development Poster Number Session	**Poster Title**
Aducanumab P1-013 Aging and dementia	EMBARK: A Phase 3b, Open-Label, Single-Arm, Safety Study to Evaluate the Long-Term Safety and Efficacy of Aducanumab in Eligible Participants with Alzheimer's Disease (Encore)

Poster presentations can be browsed at any time on the AAN website during the conference.

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<Notes to editors>

1. About the Joint Development Agreement between Eisai and Biogen for AD

Eisai and Biogen Inc. (Headquarters: Cambridge, Massachusetts, United States) are widely collaborating on the joint development and commercialization of AD treatments. Eisai serves as the lead in the co-development of lecanemab (Development Code: BAN2401), an anti-Aβ protofibril antibody, while Biogen serves as the lead for co-development of aducanumab, Biogen's investigational anti-Aβ antibody for patients with AD, and the companies plan to pursue marketing authorizations for the two compounds worldwide. If approved, the companies will also co-promote the products in major markets, such as the United States, Europe and Japan.

2. About Lecanemab (development code: BAN2401)

Lecanemab is a humanized monoclonal antibody for AD that is the result of a strategic research alliance between Eisai and BioArctic AB (Headquarters: Sweden). Lecanemab selectively binds to neutralize and eliminate soluble, toxic Aβ aggregates (protofibril) that are thought to contribute to the neurodegenerative process in AD. As such, lecanemab may have the potential to have an effect on disease pathology and to slow down the progression of the disease. Study 201 demonstrated a statistically significant slowing of disease progression and decreasing of brain Aβ accumulation as the first late-stage large-scale clinical study for early AD, and successfully showed potential disease-modifying effects. Eisai obtained the global rights to study, develop, manufacture and market lecanemab for the treatment of AD pursuant to an agreement concluded with BioArctic in December 2007. Currently, an open-label extension study (OLE) of the Phase II study (Study 201) and a pivotal clinical Phase III study (Clarity AD) of lecanemab in early AD is underway. The clinical Phase III study (AHEAD 3-45) of lecanemab in preclinical AD is also underway. The National Institutes of Health, National Institute of Aging are providing funding for the AHEAD 3-45 (A45 Study and A3 Study). Eisai and Biogen Inc. have entered into a collaboration to develop and commercialize BAN2401.

3. About Lemborexant (product name: Dayvigo)

Lemborexant, an orexin receptor antagonist, is Eisai's in-house discovered and developed small molecule that inhibits orexin neurotransmission by binding competitively to the two subtypes of orexin receptors (orexin receptor 1 and 2). Faster on/off receptor kinetics of lemborexant to orexin receptor 2, which also suppresses non-REM sleep, may influence lemborexant's potential to facilitate improvements in sleep onset and maintenance. In June 2020, lemborexant was launched under the product name DAYVIGO in the U.S. for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance; and in July 2020, it was launched under the product name DAYVIGO in Japan for the treatment of insomnia. Eisai has submitted new drug applications seeking approval of DAYVIGO in Canada, Australia and others.

4. About Perampanel (product name: Fycompa)

Perampanel is a first-in-class anti-epileptic agent (AED) discovered and developed by Eisai. With epileptic seizures being mediated by the neurotransmitter glutamate, the agent is a highly selective, noncompetitive AMPA receptor antagonist that reduces neuronal hyperexcitation associated with seizures by targeting glutamate activity at AMPA

receptors on postsynaptic membranes. Perampanel is currently approved in more than 70 countries and territories, including Japan, the United States, China, and other countries in Europe and in Asia as an adjunctive treatment for partial-onset seizures (with or without secondarily generalized seizures) in patients with epilepsy 12 years of age and older. In addition, perampanel has been approved in more than 70 countries, including the United States, Japan, in Europe and in Asia for treatment as an adjunctive therapy for primary generalized tonic-clonic seizures in patients with epilepsy 12 years of age and older. In Japan and the United States, perampanel is approved for monotherapy and adjunctive use in the treatment of partial-onset seizures (with or without secondarily generalized seizures) in patients with epilepsy 4 years of age and older. In Europe the approved age range is 4 years of age and older for the adjunctive treatment of partial-onset seizures (with or without secondarily generalized seizures) and 7 years of age and older for the treatment as an adjunctive therapy for primary generalized tonic-clonic seizure. Perampanel is available in drug form to be taken once daily orally at bedtime. A tablet and fine granule formulation have been approved in Japan. An oral suspension formulation and tablet have been approved in the United States and Europe. Eisai is conducting development of an injection formulation.

5. About Lorcaserin

By selectively activating serotonin 2C receptors in the brain, through the activation GABAergic inhibitory interneuron, expected to suppress seizure of Dravet syndrome by increasing synaptic suppression from GABAergic. Although approval for the obesity indication has been voluntarily withdrawn, due to the request from Dravet syndrome patient groups, the extended access program has been continued in the United States, and the Phase III study is underway for this indication. The FDA has designated it as an orphan drug for Dravet syndrome.

6. About Aducanumab (development code: BIIB037)

Aducanumab is an investigational human monoclonal antibody studied for the treatment of Alzheimer's disease. Based on clinical data from patients with Mild Cognitive Impairment due to Alzheimer's disease and mild Alzheimer's disease, aducanumab has the potential to impact underlying disease pathophysiology, slow cognitive and functional decline and provide benefits on patients' ability to perform activities of daily living, including conducting personal finances, performing household chores, such as cleaning, shopping and doing laundry, and independently traveling out of the home. If approved, aducanumab would be the first treatment to meaningfully change the course of the disease for individuals living with Alzheimer's disease.

Biogen licensed aducanumab from Neurimmune under a collaborative development and license agreement. Since October 2017 Biogen and Eisai have collaborated on the development and commercialization of aducanumab globally.